

REMARKS

Applicant has considered the non-final office action mailed April 30, 2009 in connection with the Application.

Application Title

Applicant notes that the specification of the Application shows a title, on page 1, as:

“Method for Recovering Peptides/Amino Acids and Oil/Fat from One of More Protein-containing Raw Materials, Products Produced by the Method, and Use of the Products.”

However, the transmittal, ancillary application filing papers, and Application Data Sheet presented to the Office on entry to the national phase in the United States use the following for the title of the Application:

“Method for Production of Peptides/Amino Acids Produced by Said Method and Use of the Same.”

The Office’s online record for the Application shows the Application has having the latter title.

Applicant hereby submits an Application Data Sheet (ADS) in the Application for the purpose of correcting the Office’s record of the application title, and conforming it to the first portion of the title shown on page 1 of the Application as-filed. Applicant understands that this change does not require a change to the application specification and therefore does not present it as an amendment to the same. Applicant makes this change so that the title is more closely reflective of the subject matter under examination.

Amendments to the Specification

Mindful of the Examiner’s objection to the spelling of “hydroxylapatite” as found in various claims, Applicant amends various instances of the same term in the specification of the Application. References herein to paragraph numbers and page numbers of the specification of the Application are made to the Substitute Specification made of record on January 27, 2005.

No new matter is believed introduced by way of these amendments, and, accordingly, entry thereof is respectfully requested.

Amendments to the Claims, and New Claims

Claims 1-41 are pending in the Application prior to entry of the instant amendments. In the instant section, it is to be assumed that reference herein to a single portion of the specification in support of a particular amendment or new claim, is not to preclude the existence of additional support for that amendment or claim, but located elsewhere in the specification and drawings, and not specifically referenced herein.

Claims 1, 5, 11, 13, 19, 30, 38, and 41, have been amended to attend to various clerical matters, including spelling of certain terms.

Claims 1 and 2 have been amended to delete various narrow range limitations where present in conjunction with broader limitations of the same ranges.

Claims 1 and 4 have been amended to recite 'a calcium base', as an adjuster of pH. Support for this amendment can be found at least at paragraph [00278] on page 30 of the Application as filed.

Claim 6 has been amended to replace "salt" by "sodium chloride". Support for this amendment is found throughout the application specification, when referring to a particular component of the hydrolysis mixture and reaction product(s), as further discussed herein.

Claims 7 – 11, 23 – 25, and 34 – 38 have been amended to delete the term "use" or "use of" from the preamble.

New Claims 42 – 44 are added, depending from claims 1 and 2 and reciting range limitations deleted from claims 1 and 2.

Accordingly, no new matter is introduced by way of the new claims herein and entry thereof is respectfully requested.

Objections to the Claims

Claim 1 is objected to for the word "hydrolysatation" in step 'f.'; Applicant has changed this term to "hydrolysis" at the Examiner's suggestion.

Claims 5 and 11, objected to for reciting "hydroxy apatite", have been amended to recite "hydroxyapatite" in its stead. Correspondingly, withdrawn claims 13, 19, 30, 38, and 41 have been also amended to correct the respective recitations of this term. In the event those claims are rejoined, delay due to the need to make these conforming amendments can thereby be obviated.

REJECTIONS OF THE CLAIMS

Rejections under 35 U.S.C. § 101

The Examiner has rejected claims 7 – 11 under 35 U.S.C. § 101 for not reciting a “proper process”. Specifically the Examiner objects to the term “use” in conjunction with a method/process recitation. Applicant has amended, herein, said claims to delete the term “use” and therefore respectfully requests that the rejection be withdrawn.

Although not specifically rejected on the same grounds, withdrawn claims 23 –25, and 34 – 38 have been similarly amended to facilitate rejoinder, if applicable, at a later date.

Rejections under 35 U.S.C. § 112 (¶ 2)

The Examiner has rejected claims 1 – 11 under 35 U.S.C. § 112 (second paragraph) as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 1 is objected to for expressing preferred ranges within a broader range, in steps ‘b’, and ‘g’. Claim 2 is similarly objected to. Applicant has amended both claims 1 and 2 herein to remove the narrower range limitation in each case, and to re-present those narrower limitations in new, dependent, claims.

Claim 1 is further objected to, at step d, for reciting ‘calcium’ as a pH adjuster. The amendment herein clarifies that the form of calcium in question is a calcium base.

Claim 1 is still further objected to for the phraseology at step f.: “pH adjuster to maintain the desired pH” and “desired pH value”. With the amendments herein, “desired” is deleted from step f. of claim 1 thereby mooted the second of these objections. The Examiner states that “[s]ince acids or bases can be used to adjust the pH of the medium ... using [buffer] instead of ‘pH adjuster’ is suggested.” (April 30, 2009 Office Action at page 4.) Applicant disagrees, however. As would be understood by those of skill in the art, the hydrolysis step can lead to a marked variation of pH over its course. Therefore, it is necessary to continually adjust the (otherwise varying) pH in order to maintain it at a value that permits the enzymes to function properly. (See, e.g., specification as filed, paragraphs [00275] – [00279] at pages 29 – 30.) Furthermore, since the specification of the Application provides a number of different pH

adjusters for achieving this outcome, Applicant disagrees that it is necessary to use a different term in claim 1.

The terms “calcium” and “nitrogen gas” in claim 4 are objected to. Applicant amends herein the term “calcium” to “a calcium base”, as discussed in connection with claim 1.

Applicant declines to amend the term “nitrogen gas” because it would be apparent to one skilled in the art that introducing nitrogen gas into an aqueous system would have some effect on pH, at least because nitrogen gas partially dissolves in water to form various nitrate counter-ions.

Finally, claim 6 is objected to for its recitation of “salt content”; the examiner recommends changing the term to sodium chloride. Applicant has done so but points out that usage of the term “salt” throughout the application specification (to mean “sodium chloride”) is consistent with the term as commonly used. (See, e.g., “fresh water and salt water”, application specification at page 20, line 1.)

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 1 – 10, under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,053,234 to Anderson *et al.*, (“Anderson” hereinafter). Claim 11 is rejected as being allegedly obvious over Anderson in view of JP-2-97409.

Applicable legal standard

The framework under which obviousness of a patent claim is judged was set forth by the U.S. Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), and is as follows. Under § 103:

- the scope and content of the prior art are to be determined;
- differences between the prior art and the claims at issue are to be ascertained; and
- the level of ordinary skill in the pertinent art resolved.

Based upon the answers to these factual enquiries, the obviousness or nonobviousness of the claimed subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might also be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Accordingly, and at a minimum, in order to establish obviousness of a claim, the prior art reference, or references when combined, must teach or suggest each and every limitation of the claimed invention. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Furthermore, and in instances where each and every limitation of the claimed invention can be found in a combination of references, an analysis of an apparent reason to combine the known elements in the fashion claimed should be made explicit. *KSR Int'l. Co. v. Teleflex Inc.*, (550 U.S. 398, 127 S. Ct. 1727 (2007)).

Applicant's claims

Claim 1 (from which all rejected claims depend) recites a method for recovering peptides/amino acids and oil/fat from protein-containing raw materials.

Examiner's rejection and cited reference(s)

Anderson describes a process for producing a “proteinaceous product by digestion of raw animal parts”. According to the Examiner, Anderson describes – at various locations therein – certain of the steps recited in Applicant’s claims. The differences between Anderson and Applicant’s claimed process are, according to the Examiner, merely variations within the skill of the artisan.

Applicant's Response to Examiner's rejection

Applicant respectfully disagrees with the Examiner’s characterization of Anderson and the variations embodied in Applicant’s claimed invention.

First, it should be noted that the method of Anderson produces a *proteinaceous* product, defined to contain “45 – 65 w/w percent partially hydrolyzed, non-denatured animal protein” (Anderson, Abstract). The proteins have a “target value for the number-average molecular weight” in the “range of about 15,000 to about 30,000 daltons” (Anderson, at col. 9, lines 11 – 13). This differs from Applicant’s method, which results in a product containing amino acids and/or peptides. These products are not non-denatured proteins. (See also, Applicant’s specification at page 5, paragraph [0027].)

Second, Applicant notes that the product of Applicant’s method has separated fat/oil from the amino acids and short peptides. (See, e.g., Applicant’s specification at page 5, paragraph

[0027]). By contrast, the Anderson method produces a mixture having “about 20 to 35 w/w percent oil derived from animal parts” (Anderson, Abstract).

Certain aspects of Applicant’s process ensure that the product produced has the qualities referenced hereinabove. For example, in Applicant’s method, proteins are coagulated and removed, for example by applying a low pH to the reaction feed. By contrast, in Anderson, proteins are beneficially caused to “self-agglomerate into proteinaceous granules” (col. 14, bottom), and remain that way in the final product.

Therefore claim 1, at least, is not obvious in view of Anderson.

Dependent claims are nonobvious under 35 U.S.C. § 103 “if the independent claims from which they depend are nonobvious.” In re Fine 837 F.2d 1071; 5 USPQ.2d 1596; MPEP 2143.03. Accordingly, claims 2 – 10 are similarly not obvious over Anderson. Since JP-2-97409 does not provide the disclosures that are missing from Anderson, claim 11 is not obvious over Anderson in combination with JP-2-97409.

By responding in the foregoing remarks only to particular positions taken by the examiner, Applicant does not acquiesce with other positions that have not been explicitly addressed. In addition, Applicant’s selecting particular arguments for the patentability of a claim should not be understood as implying that no other reasons for the patentability of that claim exist. Finally, the applicant’s decision to amend or cancel any claim should not be understood as implying that the applicant agrees with any positions taken by the examiner with respect to that claim or other claims affected by such amendments.

CONCLUSION

In view of the above remarks, Applicant respectfully submits that the Application is in good and proper order for allowance. Withdrawal of the Examiner’s rejections and early notification to this effect are earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the Application, the Examiner is encouraged to call the undersigned at (650) 839-5070.

Inventor : Tomas Carlsson
Serial No. : 10/523,151
Filed (§ 371(c)) : January 27, 2005
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Attorney Docket No.: 20166-0007US1

No fee is believed owed in connection with filing of this amendment and reply.
However, should the Commissioner determine otherwise, the Commissioner is authorized to charge any underpayment or credit any overpayment to Fish & Richardson P.C. Deposit Account No. 06-1050 (ref. no. 20166-0007US1) for the appropriate amount.

Respectfully submitted,

Date: October 30, 2009 By: /Richard G. A. Bone/ 56,637
Richard G. A. Bone (Reg. No.)

Customer Number 26181
Fish & Richardson P.C.
Telephone: (650) 839-5070
Facsimile: (650) 839-5071

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